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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WANG, SHENGJUN	

ART UNIT	PAPER NUMBER
1627	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/775,888	ENDERMANN ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,10,12 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,10,12 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted December 1, 2010 is acknowledged.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 21, 2010 has been entered.

Claim Rejections 35 U.S.C. 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 2, 10, 12 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "betaine" in claim 1 is used by the claim to mean "zwitterionic compound" (as now applicants argued), while the accepted meaning is "A **betaine** in chemistry is any neutral chemical

compound with a positively charged cationic functional group such as an quaternary ammonium or phosphonium cation (generally: onium ions) which bears no hydrogen atom and with a negatively charged functional group such as a carboxylate group which may not be adjacent to the cationic site. A betaine thus may be a specific type of zwitterion. Historically the term was reserved for trimethylglycine only." The term is indefinite because the specification does not clearly redefine the term.

Claim Rejections 35 U.S.C. 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Because of the ambiguity of the claims (see the rejection above), the claims are interpretated broadly to encompass both the compound represented by formula (III) its betaine salts.

3. Claims 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Pikiewicz et al. (US 2004/0009126 A1).

4. Pikiewicz et al. teach a method of treating bacterial lung infection comprising locally administration of ciprofloxacin by inhalation, wherein the ciprofloxacin is in the form of particle and may be in the form of dry powder. See, particularly, the abstract, paragraphs [0064] and [0069], and the claims.

Claim Rejections 35 U.S.C. 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer et al. in view of Li et al.

Mayer et al. treated anthrax lung infection by administering to the patients ciprofloxacin. The administration is carried out intravenously. See, particularly, the abstract, pages 2550 and 2551. Mayer et al. further disclosed that it is well known that ciprofloxacin is effective against anthrax and is a standard treatment of anthrax. See, page 252, the right column.

Mayer et al. do not teach expressly local administration as herein claimed.

However, Li et al. teach ciprofloxacin administration intravenously or orally have relatively unfavorable pharmacokinetic profile in the lower respiratory track. Li also disclosed that Aerosol inhalation as means of drug delivery to the respiratory tract has been well established in the treatment of lung disease, and dry powder inhaler have received increasing attention in the art. Li et al. further teaches a ciprofloxacin loaded particles for dry powder inhaler delivery to the respiratory track by inhalation. See, particularly, the abstract and introduction at page 825.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use dry powder inhaler for delivery

ciprofloxacin composition, such as those disclosed by Li, directly to respiratory track for treatment of respiratory track bacterial infection, such as anthrax infection.

A person of ordinary skill in the art would have been motivated to use dry powder inhaler for delivery ciprofloxacin composition, such as those disclosed by Li, directly to respiratory track for treatment of respiratory track bacterial infection, such as anthrax infection because the delivery method is more effective than intravenous or oral delivery. As to patient's conditions recited in claim 15, note, an antibiotics agent known to be useful against bacterial infection would have expected to effective against the bacterial infection in patients with other medical conditions. Therefore, one of ordinary skill in the art would have been motivated to treat the bacterial infection of patients with cystic fibrosis, chronic obstructive pulmonary disease or bronchiactasis.

7. Claims 1, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pikiewicz et al. (US 2004/0009126 A1) in view of Kanikanti et al. (WO 02/00219 A1, US 2004/0024018 A1 is a English equivalence).

8. Pikiewicz et al. teach a method of treating bacterial lung infection comprising locally administration of ciprofloxacin by inhalation, wherein the ciprofloxacin or its salt, is in the form of particle and may be in the form of dry powder. See, particularly, the abstract, paragraphs [0064] and [0069], and the claims.

9. Pikiewicz et al. do not teach expressly the employment of the particular salt, ciprofloxacin betaine.

10. However, Kanikanti et al. teaches that ciprofloxacin betaine is a known salt of ciprofloxacin useful for therapeutical purpose. See, particularly, paragraphs [0039]-[0047].

11. Therefore, it would have been obvious to use ciprofloxacin betaine as a ciprofloxacin salt in Pikiewicz's method.

12. A person of ordinary skill in the art would have been motivated to use ciprofloxacin betaine as a ciprofloxacin salt in Pikiewicz's method because ciprofloxacin betaine is one of few known salt of ciprofloxacin. Furthermore, as stated in KSR vs. Teleflex, where the court states:

"When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. **If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.** In that instance the fact that a combination was obvious to try might show it was obvious under section 103." In the instant case, it would have been obvious to try the known salts of ciprofloxacin for an optimal therapeutical result. Since there are not many known ciprofloxacin salts. As to patient's conditions recited in claim 15, note, an antibiotics agent known to be useful against bacterial infection would have expected to effective against the bacterial infection in patients with other medical conditions. Therefore, one of ordinary skill in the art would have been motivated to treat the bacterial infection of patients with cystic fibrosis, chronic obstructive pulmonary disease or bronchiactasis.

13. Claims 1, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer et al. in view of Li et al. and Kanikanti et al. (WO 02/00219 A1, US 2004/0024018 A1 is a English equivalence).

Mayer et al. treated anthrax lung infection by administering to the patients ciprofloxacin. The administration is carried out intravenously. See, particularly, the abstract, pages 2550 and 2551. Mayer et al. further disclosed that it is well known that ciprofloxacin is effective against anthrax and is a standard treatment of anthrax. See, page 252, the right column.

Mayer et al. do not teach expressly local administration as herein claimed or the employment of ciprofloxacin betaine.

14. However, Li et al. teach ciprofloxacin administration intravenously or orally have relatively unfavorable pharmacokinetic profile in the lower respiratory track. Li also disclosed that Aerosol inhalation as means of drug delivery to the respiratory tract has been well established in the treatment of lung disease, and dry powder inhaler have received increasing attention in the art. Li et al. further teaches a ciprofloxacin loaded particles for dry powder inhaler delivery to the respiratory track by inhalation. See, particularly, the abstract and introduction at page 825. Kanikanti et al. teaches that ciprofloxacin betaine is a known salt of ciprofloxacin useful for therapeutical purpose. See, particularly, paragraphs [0039]-[0047].

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use dry powder inhaler for delivery ciprofloxacin composition, such as ciprofloxacin betaine, directly to respiratory track for treatment of respiratory track bacterial infection, such as anthrax infection.

A person of ordinary skill in the art would have been motivated to use dry powder inhaler for delivery ciprofloxacin composition, such as such as ciprofloxacin betaine, directly to respiratory track for treatment of respiratory track bacterial infection, such as anthrax infection

because the delivery method is more effective than intravenous or oral delivery, and ciprofloxacin betaine is a known salt of ciprofloxacin useful for therapeutical purpose. As to patient's conditions recited in claim 15, note, an antibiotics agent known to be useful against bacterial infection would have expected to effective against the bacterial infection in patients with other medical conditions. Therefore, one of ordinary skill in the art would have been motivated to treat the bacterial infection of patients with cystic fibrosis, chronic obstructive pulmonary disease or bronchiactasis.

Response to the Arguments

15. Applicants' amendments and remarks submitted December 1, 2010 have been fully considered, but are not persuasive.

16. Applicants concede that "betaine" applicants intended to means herein is not art acceptable conventional definition, but argue that "ciprofloxacin betaine or enrofloxacin betaine" are art recognized terms, citing several US patent literatures and other publications. The arguments are not tenable. Indeed, all the references cited by applicants recited ciprofloxacin betaine, but none of them gives clear metes and bounds for the scopes of these terms as what applicants' envisaged. None of cited references provides formal clear non-conventional definition, and to less extend, the applicants argued definition. Therefore, one of ordinary skill in the art would have not recognized the metes and bounds of the scopes of "ciprofloxacin betaine or enrofloxacin betaine" as applicants envisaged. In fact art recognized definition of "ciprofloxancin betaine" is a betaine (N,N,N-trimethylglycine) salt of ciprofloxancin. See, STN registration file: Ciprofloxacin betaine.

The rejections of claims 1 and 15 under 35 U.S.C 102 and 103 are maintained as the terms of "ciprofloxacin betaine or enrofloxacin betaine" are given broadest interpretation.

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/
Primary Examiner, Art Unit 1627